

Listing of Claims:

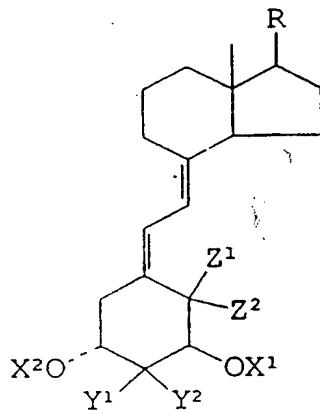
1. (Previously Amended) A method of reducing the risk of Type 1 diabetes in a predisposed human patient by up to 90 percent, comprising the steps of:

identifying a human patient predisposed to Type 1 diabetes; and

orally administering to the patient an effective amount of a 1α -hydroxy vitamin D compound such that the risk of onset of Type 1 diabetes or Type 1 diabetes symptoms is reduced.

2. (Original) The method of claim 1 wherein the compound is selected from the group consisting of $1\alpha,25$ -dihydroxyvitamin D₃ ($1,25-(OH)_2D_3$), 19-nor- $1,25$ -dihydroxyvitamin D₂ (19-nor- $1,25-(OH)_2D_3$), 24-homo-22-dehydro-22E- $1\alpha,25$ -dihydroxyvitamin D₃ (24-homo-22-dehydro-22E- $1,25-(OH)_2D_3$), 1,25-dihydroxy-24(E)-dehydro-24-homo-vitamin D₃ ($1,25-(OH)_2-24$ -homo D₃), 19-nor- $1,25$ -dihydroxy-21-epi-vitamin D₃ (19-nor- $1,25-(OH)_2-21$ -epi-D₃), 1α hydroxy vitamin D₃ or 1α hydroxy vitamin D₂.

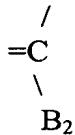
3. (Previously Amended) The method of claim 1 wherein the vitamin D compound is selected from the group consisting of vitamin D compounds with the following formula:



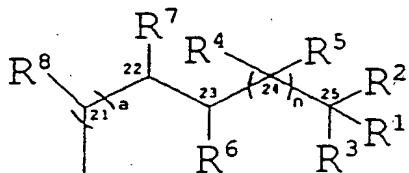
Appl. No. 09/769,579
Amtd. Dated February 8, 2005
Reply to Office Action of September 9, 2004

wherein X¹ and X² are each selected from the group consisting of hydrogen and acyl; wherein Y¹ and Y² are each selected from the group consisting of H, 0-aryl, 0-alkyl, aryl, and alkyl of 1-4 carbons, taken together to form an alkene having the

structure of B₁



where B₁ and B₂ are selected from the group consisting of H, alkyl of 1-4 carbons and aryl, and can have a β or α configuration; Z¹=Z²=H or Z¹ and Z² together are =CH₂; and wherein R is an alkyl, hydroxyalkyl or fluoroalkyl group, or R represents the following side chain:



wherein (a) may have an S or R configuration, R¹ represents hydrogen, hydroxy or O-acyl, R² and R³ are each selected from the group consisting of alkyl, hydroxyalkyl and fluoralkyl, or, when taken together represent the group-(CH₂)_m-wherein m is an integer having a value of from 2 to 5, R⁴ is selected from the group consisting of hydrogen, hydroxy, fluorine, O-acyl, alkyl, hydroxyalkyl and fluoralkyl, wherein if R⁵ is hydroxyl or fluoro, R⁴ must be hydrogen or alkyl, R⁵ is selected from the group consisting of hydrogen, hydroxy, fluorine, alkyl, hydroxyalkyl and fluoroalkyl, or R⁴ and R⁵ taken together represent double-bonded oxygen, R⁶ and R⁷ taken together form a carbon-carbon double bond, R⁸ may be H or CH₃, and

wherein n is an integer having a value of from 1 to 5, and wherein the carbon at any one of positions 20, 22, or 23 in the side chain may be replaced by an O, S, or N atom.

4. (Original) The method of claim 1 wherein the oral administration is via diet.

5. (Original) The method of claim 1 wherein the oral administration is at the concentration of between 0.005 μg to 0.2 μg per kilogram of patient weight per day.

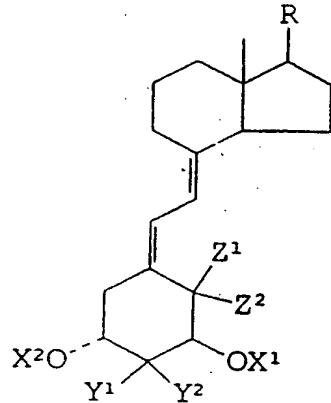
Claims 6 – 10 (Cancelled)

11. (Previously Presented) A method of reducing the risk of Type 1 diabetes in a predisposed human patient by up to 90 percent, comprising the steps of:

identifying a human patient predisposed to Type 1 diabetes, wherein Type 1 diabetes is detectable in a patient with autoantibodies to glutamic acid decarboxylase; and
orally administering to the patient an effective amount of a 1α -hydroxy vitamin D compound such that the risk of onset of Type 1 diabetes or diabetes symptoms is reduced.

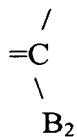
12. (Previously Presented) The method of claim 11 wherein the compound is selected from the group consisting of $1\alpha,25$ -dihydroxyvitamin D₃ ($1,25-(\text{OH})_2\text{D}_3$), 19-nor- $1,25$ -dihydroxyvitamin D₂ (19-nor- $1,25-(\text{OH})_2\text{D}_3$), 24-homo-22-dehydro- $22\text{E}-1\alpha,25$ -dihydroxyvitamin D₃ (24-homo-22-dehydro- $22\text{E}-1,25-(\text{OH})_2\text{D}_3$), $1,25$ -dihydroxy- $24(\text{E})$ -dehydro-24-homo-vitamin D₃ ($1,25-(\text{OH})_2-24-\text{homo D}_3$), 19-nor- $1,25$ -dihydroxy- 21 -epi-vitamin D₃ (19-nor- $1,25-(\text{OH})_2-21-\text{epi-D}_3$), 1α hydroxy vitamin D₃ or 1α hydroxy vitamin D₂.

13. (Previously Presented) The method of claim 11 wherein the vitamin D compound is selected from the group consisting of vitamin D compounds with the following formula:

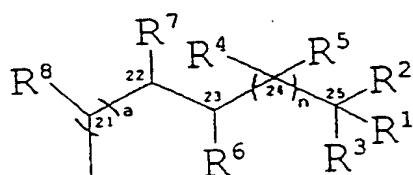


wherein X^1 and X^2 are each selected from the group consisting of hydrogen and acyl; wherein Y^1 and Y^2 are each selected from the group consisting of H, 0-aryl, 0-alkyl, aryl, and alkyl of 1-4 carbons, taken together to form an alkene having the

structure of B_1



where B_1 and B_2 are selected from the group consisting of H, alkyl of 1-4 carbons and aryl, and can have a β or α configuration; $Z^1=Z^2=H$ or Z^1 and Z^2 together are $=CH_2$; and wherein R is an alkyl, hydroxyalkyl or fluoroalkyl group, or R represents the following side chain:



wherein (a) may have an S or R configuration, R¹ represents hydrogen, hydroxy or O-acyl, R² and R³ are each selected from the group consisting of alkyl, hydroxyalkyl and fluoralkyl, or, when taken together represent the group-(CH₂)_m-wherein m is an integer having a value of from 2 to 5, R⁴ is selected from the group consisting of hydrogen, hydroxy, fluorine, O-acyl, alkyl, hydroxyalkyl and fluoralkyl, wherein if R⁵ is hydroxyl or fluoro, R⁴ must be hydrogen or alkyl, R⁵ is selected from the group consisting of hydrogen, hydroxy, fluorine, alkyl, hydroxyalkyl and fluoroalkyl, or R⁴ and R⁵ taken together represent double-bonded oxygen, R⁶ and R⁷ taken together form a carbon-carbon double bond, R⁸ may be H or CH₃, and wherein n is an integer having a value of from 1 to 5, and wherein the carbon at any one of positions 20, 22, or 23 in the side chain may be replaced by an O, S, or N atom.

14. (Previously Presented) The method of claim 11 wherein the oral administration is via diet.

15. (Previously Presented) The method of claim 11 wherein the oral administration is at the concentration of between 0.005 μg to 0.2 μg per kilogram of patient weight per day.